CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

210 King Street
San Francisco, CA 94107

Request For Information 08-01

Provision of Human Embryonic Stem Cell Lines to CIRM Grantees

Responses due: November 21, 2008

1.0 Introduction

The California Institute for Regenerative Medicine (CIRM) was established in 2004 with passage of Proposition 71, the California Stem Cell Research and Cures Act. This statewide ballot measure provided $3 billion in funding for stem cell research at California universities, industries, and research institutions and called for the establishment of an entity (CIRM) to make grants and provide loans for stem cell research, research facilities, and related vital research opportunities. To date, the CIRM governing board has approved 229 research and training grants totaling more than $614 million dollars. CIRM funds Grantees at California academic institutions, non-profit organizations, and for-profit organizations, who are engaged in basic and translational research utilizing human embryonic stem cells (hESC) and other stem cells. For more information, please visit www.cirm.ca.gov.

Human embryonic stem cells are integral to basic and translational research by CIRM Grantees. Embryonic sources currently provide the only significant means of producing human pluripotent stem cells that are genetically and epigenetically unmanipulated. Furthermore, in order to create cellular models of heritable disease, researchers are deriving hESC lines from embryos carrying mutations that predispose to or cause disease. The use of disease-specific or otherwise genotypically diverse hESC lines that can differentiate into many cell types will have great value for drug discovery and toxicology testing. Thus, in addition to the derivation of new hESC lines, easy access to already existing hESC lines (other than the NIH registered hESC lines) would enable rapid progress toward basic and translational research goals. However, researchers

often encounter barriers when attempting to acquire hESC generated by others. Thus, CIRM requests information about how to structure a new program that will address the need of CIRM Grantees to have reliable and cost-effective access to hESC lines.

2.0 RFI Objectives

The purpose of this Request For Information (RFI) is to gain insight that will guide CIRM in establishing a mechanism to facilitate reliable, cost-effective access to high-quality hESC lines for CIRM Grantees. To achieve this goal, CIRM is seeking responses from providers of non-NIH registered hESC lines, describing available hESC lines and suggesting a mechanism that facilitates their acquisition by CIRM Grantees. This RFI may guide CIRM in structuring a Request for Proposals (RFP) for provision of hESC lines to CIRM grantees.

3.0 Information Being Requested

The goal of this RFI is to establish the numbers and types of hESC lines that are available for distribution, to understand their quality and cost, to understand the barriers that limit access to the lines, and to discover incentives that would encourage potential suppliers to provide discounts to CIRM Grantees. CIRM is requesting information regarding, but not limited to, the following areas:

(a) Describe the number and types of hESC lines that you can supply and how your lines would be useful to the research of CIRM Grantees.

(b) Provide detailed information about the derivation and handling of your hESCs.

(c) Describe how your hESC lines were characterized, and what quality control they undergo.

(d) Verify that your hESC lines are acceptably derived in accordance with CIRM's Medical and Ethical Standards (CIRM MES Regulations Title 17 California Code of Regulations Section 100010-100120 at http://www.cirm.ca.gov/reg/default.asp).

(e) Comment on whether your hESC lines are easy to obtain (time from order to delivery) and their current cost. Explain the factors, other than cost, that contribute to making your cell lines easy or difficult to obtain.

(f) Describe any impediments to the ability of CIRM Grantees to gain access to your hESCs. Suggest tools and resources that CIRM can provide to overcome these impediments.

(g) Suggest how best to structure a distribution arrangement for hESC lines to CIRM Grantees.

(h) Describe how a program to provide discounts for CIRM Grantees could be best administered.

(i) Describe an appropriate administrative structure that would enable CIRM Grantees to submit requests for and receive the hESC lines.

(j) Explain how material transfer agreements for the hESC lines would be negotiated with CIRM Grantees.

4.0 Instructions for Responding to this RFI

4.1 Who May Respond

Responses from ***anyone*** in industry, government or academia with practical knowledge of the provision of human embryonic stem cell lines to CIRM Grantees are welcome.

4.2 How to Respond

One electronic copy in machine-readable format (typically MS Word, or Adobe PDF) should be sent to ***RFIresponse@cirm.ca.gov.*** One confirming paper copy of all documents should be sent to CIRM at the address below.

California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
USA
Attn: *Cynthia Schaffer*
RE: RFI 08-01

Responses to this RFI must be received at CIRM no later than 5:00 PM, November 21, 2008.

4.3 RFI Response Contact

Companies, institutions, and individuals responding to this RFI shall designate a single contact for receipt of all subsequent information regarding this RFI and any related RFPs.

4.4 Format of RFI Responses

The following outline is offered to assist in the development of your response. You should include:

- A cover letter that summarizes your response, including the areas of focus of your response, and indicating if supporting documentation is included in your response.
- The response itself, covering any or all of the areas of information requested by this RFI (see section 3).

Please limit the size of your response (not counting any supporting documentation) to 25 pages. If supporting documentation is necessary, please indicate which portions of the supporting documentation are relevant to which area of information.

4.5 Reimbursement

CIRM will not reimburse submitters for any costs in conjunction with their responses to this RFI.

4.6 Questions Regarding this RFI

Questions should be addressed to:
Uta Grieshammer, Ph.D.
Scientific Officer
Email: ugrieshammer@cirm.ca.gov
Phone: (415) 396-9118
Fax: (415) 396-9141

5.0 Response Review: Process and Schedule

5.1 Distribution and Disposition of RFI Responses

Copies of all documentation submitted in response to this RFI will be available to CIRM staff for review purposes. All documents received in response to this RFI will become the property of CIRM, and will be regarded as public records under the California Public Records Act (Government Code Section 6250 et seq.) and therefore may become subject to review by the public. For more information please see CIRM's public records access guidelines at http://www.cirm.ca.gov/faq/pdf/guidelines.pdf.

5.2 Review Process & Clarification

CIRM Staff will review responses to this RFI. To fully comprehend the information contained within a response to this RFI, the reviewing group may seek further clarification of a response. This clarification may be requested in the form of brief verbal communication by telephone; written communication; electronic communication; or a presentation to CIRM Staff.

5.3 RFI Response Presentations and Demonstrations

RFI Respondents may be invited to present their response to CIRM Staff. The purpose of this presentation would be to seek clarification of information contained within the response (as noted above); to further explore issues raised; or to further meet the goals of the RFI.

5.4 Schedule

The schedule for responding to this RFI is as follows. Please note that early responses are encouraged.

RFI issued:	*October 10, 2008*
RFI responses due:	*November 21, 2008*
Review of RFI responses:	*through December 2008*

Appendix A References and Glossary Specific to this RFI

http://stemcells.nih.gov/research/registry/

http://www.nationalstemcellbank.org/

Human Stem Cell and Tissue Research Regulations

All research funded by CIRM is expected to comply with CIRM MES standards that can be viewed at http://www.cirm.ca.gov/reg/default.asp).